Experiential Learning Program (ELP) – Sample Site Visit Request and Agenda*

Area of interest addressed:	Total product life cycle of [insert medical device specialty]
Contact person:	Wendy Schumer Senior Vice President, Regulatory Affairs Medical Devices, Inc. 123 Technology Way Generic City, TX 55555 Phone: 555-123-4567 Email: wschumer@gmd.com
Site visit location:	Medical Devices, Inc. 123 Technology Way Generic City, TX 55555
Length of site visit:	2 Days
Proposed dates:	June 3 - 4, 2014 Week of June 9, 2014 July 16 - 17, 2014 Week of August 4, 2014
Maximum number of CDRH participants that can be accommodated:	10
Travel recommendations:	(Closest airport, recommended hotels)

**To ensure the site visit adequately addresses the specific training need, for each topic below in the agenda, please provide a detailed description of the content to be covered during that session. This information can be presented as a separate document (e.g., course curriculum outline) or embedded within the agenda.*

Day 1

Time	Topic	Presenter(s)	Location
9:00 - 9:15 a.m.	Introductions	James Bentley *Regulatory Affairs Specialist* Wendy Schumer *Senior Vice President, Regulatory Affairs*	Medical Devices, Inc. 123 Technology Way Generic City, TX 55555 Building 1, Room 1422
9:15 - 9:30 a.m.	Overview of site visit – day 1	James Bentley *Regulatory Affairs Specialist*	Building 1, Room 1422
9:30 - 9:45 a.m.	Preparation to visit animal lab	Wendy Schumer *Senior Vice President, Regulatory Affairs*	Building 1, Room 1422
9:45 - 11:00 a.m.	Animal lab – Surgical technique training	Hal Smith *Director, Animal Laboratory*	Building 3, Room 3286
11:00 -12:00 p.m.	Animal lab – Question and Answer	James Bentley *Regulatory Affairs Specialist*	Building 1, Room 1422
12:00 - 1:00 p.m.	Lunch	Not Applicable	Building 1, Cafeteria
1:00 - 1:15 p.m.	Preparation to visit manufacturing floor	James Bentley *Regulatory Affairs Specialist*	Building 1, Room 1422
1:15 - 2:15 p.m.	Tour of manufacturing facility	John Hansen *Director of Quality Systems*	Building 5
2:15 - 3:00 p.m.	Manufacturing – Question and Answer	James Bentley *Regulatory Affairs Specialist*	Building 5, Room 1100
3:00 - 3:15 p.m.	Preparation to visit non-clinical lab	James Bentley *Regulatory Affairs Specialist*	Building 5, Room 1100
3:00 - 4:00 p.m.	Non-clinical lab – Mechanical testing	Alison Moyet *Senior Engineer*	Building 1, Room G375
4:00 - 5:00p.m.	Mechanical testing – Question and Answer	Alison Moyet *Senior Engineer*	Building 1, Room G375

Day 2

Time	Topic	Presenter(s)	Location
7:00 - 7:15 a.m.	Overview of site visit – day 2	James Bentley *Regulatory Affairs Specialist*	Medical Devices, Inc. 123 Technology Way Generic City, TX 55555 Central Administration Building, Room 214
7:15 - 7:45 a.m.	Preparation for operating room	Dr. William Jenkins *Surgeon*	Hancock Building 5th Floor
7:45 - 10:30 a.m.	Observe Implantation Surgery	Dr. William Jenkins *Surgeon*	Hancock Building 5th Floor
10:30 - 11:00 a.m.	Change/Travel to conference room/Break	James Bentley *Regulatory Affairs Specialist*	Hancock Building 5th Floor
11:00 - 11:30 a.m.	Implantation Surgery – Question and Answer	Dr. William Jenkins *Surgeon*	Central Administration Building, Room 214
11:30 - 12:30 p.m.	Lunch	Not Applicable	Central Administration. Building, Cafeteria
12:30 - 2:30 p.m.	Retrieval analysis – Integrating field experience	James Bentley *Regulatory Affairs Specialist*	Central Administration Building, Room 214
2:30 - 2:45 p.m.	Retrieval analysis – Question and Answer	James Bentley *Regulatory Affairs Specialist*	Central Administration Building, Room 214
2:45 - 3:00 p.m.	Closing remarks	Wendy Schumer *Senior Vice President, Regulatory Affairs*	Central Administration Building, Room 214